REMARKS

Claims 1-2, 4-7, 10, 13-15, 17-20, 24-25, 28-30, 32-35, 38, 42-62 and 64-81 are currently pending in the application. Claims 3, 8-9, 11-12, 16, 21-23, 26-27, 31, 36-37, 39-41 and 63 are canceled without prejudice to or disclaimer of the subject matter therein.

The Office Action has required election of a single target 3'-UTR polynucleotide from claims 1, 10, 14, 24, 28, 36, 43 and 57.

Applicants respectfully point out that the Office Action's Restriction Requirement is improper for several reasons. First, the Office Action's requirement to elect a single target 3'-UTR polynucleotide from claims 1, 10, 14, 24, 28, 36, 43 and 57 is wrong, because *there is only one 3' UTR polynucleotide*. The claims recite conserved target ribonucleotide sequences that are selected from the group consisting of a) 5'-untranslated region (5'-UTR); b) the 3'-untranslated region (3'-UTR); c) the core; d) NS5, and e) NS3 helicase. Each conserved ribonucleotide sequence is a domain necessary for HCV replication (*see* Figure 2 in the application).

Second, the Office Action's restriction is improper because it improperly restricts within a Markush group of species. Case law has established the judicially created doctrine of "Markush practice": *"A Markush-type claim is directed to "independent and distinct inventions," if two or more of its members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s)". In re Weber, Soder, and Boksay*, 198 U.S.P.Q. 328 at 332. *"However, when a Markush grouping does not contain "independent and distinct" inventions, "the substances grouped have a 'community of chemical or physical characteristics' which justify their inclusion in a common group, and that such inclusion is not repugnant to principles of scientific classification."* *In re Jones*, 74 U.S.P.Q. 149 at 151.

The M.P.E.P. § 803.02 sets forth the criteria for unity of invention within Markush-type claims. According to the M.P.E.P. guidelines, it is sufficient for the members of the Markush group to belong to a recognized physical or chemical class or to an art-recognized class to satisfy the unity of invention requirement.

Furthermore, the M.P.E.P. notes that the Examiner should not require a restriction when the members of the Markush group share a common function and a structural feature essential for their function:

> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

In this case, the target ribonucleotide sequences recited in the claims are all conserved domains necessary for HCV replication, and thus are functionally and biologically related.

Third, the M.P.E.P. also states that in the absence of serious burden, all member of the Markush group must be examined on the merit:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions.

In the present application, the search required to examine any of the nucleotide sequences recited in the claims overlaps and therefore cannot constitute an undue burden.

Fourth, while the M.P.E.P contemplates applications containing a Markush-type claim that encompass at least two independent or distinct inventions, it also states that " the examiner may require a provisional election of a single species *prior to* examination on the merits" (emphasis added). Thus, even *arguendo*, that the present claims recite independent or distinct species within the Markush group, the Office Action may require a provisional election of species, in which case "*should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended*". The M.P.E.P. further states that "*the examination will be extended to the extent necessary to determine patentability of the Markush-type claim*". Thus, the restriction requirement improperly applied to Markush-type claims in the present application is impermissible.

Fifth, an Office Action on the merits was issued in this application prior to the restriction requirement. Thus, all the sequences claimed in the present application have been already searched and examined. The Notice rescinding the partial waiver of 37 C.F.R. § 1.141 et seq. for restriction practice in national applications, which was issued by the U.S. Patent and Trademark Office on February 22, 2007, sets forth the criteria necessary for the examination of nucleotide sequences and states: "*supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances*".

For at least the reasons stated above, the Office Action's restriction requirement is improper. Therefore, Applicants respectfully request that the restriction requirement be withdrawn and all the target nucleic acid sequences encompassed by the pending claims be examined.

Without acquiescing to the property of the restriction requirement, but solely to properly respond to the restriction requirement, Applicants provisionally elect, with traverse, the 5'-untranslated region (5'-UTR) conserved ribonucleotide sequence in the hepatitis C virus genome,

and specifically the nucleic acid sequence siRNA5 recited in the claims, for examination. All pending claims are readable for prosecution in the subject application, and at least claims 1, 10, 14, 24, 28, 36, 43 and 57 are generic. Applicants also reserve the right to have the non-elected species examined when the elected claims are allowed (including any claims depending from any allowed generic claim), and further to file one or more divisional applications covering the subject matter of the non-elected species, as appropriate.

Respectfully submitted,

Date May 15, 2007 By Richard Peet

FOLEY & LARDNER LLP
Customer Number: 27476
Telephone: (202) 672-5483
Facsimile: (202) 672-5399

Richard C. Peet
Attorney for Applicants
Registration No. 35,792

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